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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/752,145	12/29/2000	Klim King	CPI-013CNDV4	8048
959	7590	09/09/2002		
LAHIVE & COCKFIELD 28 STATE STREET BOSTON, MA 02109			EXAMINER	ULM, JOHN D
			ART UNIT	PAPER NUMBER
			1646	
DATE MAILED: 09/09/2002 <u>g</u>				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/752,145

Applicant(s)

King et al.

Examiner

John Ulm

Art Unit

1646



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on Jun 17, 2002

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-9 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-9 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some* c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. _____.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892)

4) Interview Summary (PTO-413) Paper No(s). _____

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

5) Notice of Informal Patent Application (PTO-152)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

6) Other: _____

Art Unit: 1646

- 1) Claims 1 to 9 are pending in the instant application. Claims 1, 4 and 7 have been amended as requested by Applicant in Paper Number 8, filed 17 June of 200 .
- 2) Any objection or rejection of record which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.
- 3) The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
- 4) Claims 1 to 7 stand rejected under 35 U.S.C. § 103 as being unpatentable over the Marullo et al. patent (5,242,822) in view of the Dietzel et al. (Cell 50:1001-1010, 25 Sep. 1987), Herskowitz et al. (Cell 50:995-996, 25 Sept. 1987) and Whiteway et al. (Cell 56:467-477, 10 Feb. 1989) publications for those reasons of record in section 3 of Paper Number 6.

Applicant has traversed this rejection on the premise that it is incompatible with a rejection of these claims under 35 U.S.C. § 112, first paragraph, because the combined rejections create some sort of "inappropriate" "squeeze". Applicant is legally in error. First, the word "squeeze" appears nowhere in the M.P.E.P. and, therefore, is not a legal concept recognized by the USPTO. Second, a claim can be rejected under 35 U.S.C. § 101 and 35 U.S.C. § 112, first paragraph, as inoperable in the same action which rejects that claim under 35 U.S.C. § 102 as anticipated by the prior art as well as under 35 U.S.C. § 103 as being obvious in view of the prior art (*Ex parte Dash*, 27 USPQ2d 1481 (BdPatApp&Int, 1993)). Third, the instant claims were not rejected under 35 U.S.C. § 112, first paragraph, for complete lack of enablement. They were rejected because the instant specification was not enabling for the practice of that portion of the subject

Art Unit: 1646

matter encompassed by the claims which did not include the critical relationship “that the mammalian G protein-coupled receptor employed in the claimed cell must be capable of coupling to (compatible with) the mammalian G α subunit employed therein”. Applicant has failed to identify any error in the original rejection of claims 1 to 9 under 35 U.S.C. § 112, first paragraph, and has chosen to avoid that rejection by amending the claims to contain this critical element. Because the basis for the original rejection of the instant claims under 35 U.S.C. § 112, first paragraph, was not applicable to the obvious embodiment over which they were rejected under 35 U.S.C. § 103, there is no logical conflict in the application of both of these rejections to the same claims.

In response to applicant's argument that the examiner has combined an excessive number of references, reliance on a large number of references in a rejection does not, without more, weigh against the obviousness of the claimed invention. See *In re Gorman*, 933 F.2d 982, 18 USPQ2d 1885 (Fed. Cir. 1991). In the instant rejection, the Marullo et al. and Dietzel et al. references, taken alone, provide all of the elements of the claimed invention. Marullo et al. provided a yeast cell comprising a recombinant DNA encoding a heterologous G protein-coupled receptor and Dietzel et al. provided a yeast cell comprising a recombinant DNA encoding a heterologous G α subunit. However, an obviousness rejection requires more than a suggestion that the claimed invention should be made. It must also provide a reasonable expectation of success. The Herskowitz et al. and Whiteway et al. references have been included in the instant rejection because, in conjunction with the Marullo et al. and Dietzel et al. references, they clearly

Art Unit: 1646

show that the G protein/G protein-coupled receptor systems in yeast and mammals were known to be structurally and functionally analogous at the time that the instant invention was made. Therefore, the overwhelming preponderance of evidence provided by these four publications supports a conclusion that an artisan had substantially more than a reasonable expectation that a mammalian G protein-coupled receptor and a compatible mammalian G α subunit could be functionally expressed in a yeast cell and that the activation of that receptor by an agonist thereto would produce a measurable physiological response as described in the Dietzel et al. reference.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Applicant has traversed the instant rejection on the premise that the rat G α subunit of Dietzel et al. was not capable of completely complementing the SCG1 gene mutation in the yeast cells employed therein. Essentially, Dietzel et al. discloses that the rat G α subunit did not possess all of the biological activities of the corresponding yeast G α subunit. Applicant is advised that complete SCG1 complementation was never required in support of the instant rejection. The instant rejection is based upon the premise that a measurable biological response was produced in yeast cells by a heterologous rat G α subunit when that subunit was activated by an endogenous, ligand activated G protein-coupled receptor. The fact that the activation of the rat G α subunit by yeast receptors produced a measurable response is supported by the statement concluding the

Art Unit: 1646

second paragraph on page 1006 of Dietzel et al. that “[c]onsidering the large evolutionary distance between SCG1 and the rat α_s gene, the complementation of both the *sst2* and *scg1* defects by the rat α_s gene is striking”.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

5) Claims 8 and 9 stand rejected under 35 U.S.C. 103(a) as being unpatentable over the Marullo et al.(U.S./ Pat. No. 5,242,822), Dietzel et al. (Cell 50:1001-1010, 25 Sep. 1987), Herskowitz et al. (Cell 50:995-996, 25 Sept. 1987) and Whiteway et al. (Cell 56:467-477, 10 Feb.. 1989) references. as applied to claims 1 to 7 above, and further in view of the Nomoto et al. publication (EMBO J. 9(3):691-696, March 1990) for those reasons of record on page 7 of Paper Number 6.

6) **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

Art Unit: 1646

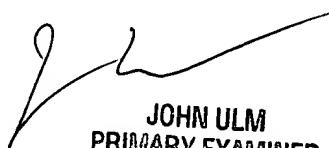
MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (703) 308-4008. The examiner can normally be reached on Monday through Friday from 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (703) 308-6564.

Official papers filed by fax should be directed to (703) 308-4242 or (703) 872-9306. Official responses under 37 C.F.R. § 1.116 should be directed to (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



JOHN ULM
PRIMARY EXAMINER
GROUP 1800